CONNELL FOLEY LLP
ATTORNEYS AT LAW

85 LIVINGSTON AVENUE
ROSELAND, NJ 07068-3702
(973) 535-0500
FAX: (973) 535-9217

OTHER OFFICES

HARBORSIDE FINANCIAL CENTER
2510 PLAZA FIVE
JERSEY CITY, NJ 07311
(201) 521-1000
FAX: (201) 521-0100

888 SEVENTH AVENUE
9TH FLOOR
NEW YORK, NY 10106
(212) 307-3700
FAX: (212) 262-0500

1500 MARKET STREET
12TH FLOOR
EAST TOWER
PHILADELPHIA, PA 19102
(215) 246-3403
FAX: (215) 665-5727

LIBERTY VIEW
457 HADDONFIELD ROAD
SUITE 230
CHERRY HILL, NJ 08002
(856) 317-7100
FAX: (856) 317-7117

THE ATRIUM, SUITE E
309 MORRIS AVENUE
SPRING LAKE, NJ 07762
(732) 449-1440
FAX: (732) 449-0934

JOHN A. PINDAR (1969)
GEORGE W. CONNELL (2005)
ADRIAN M. FOLEY, JR.
GEORGE J. KENNY*
KENNETH F. KUNZMAN
SAMUEL D. LORD (2012)
RICHARD D. CATENACCI
RICHARD J. BADOLATO*
PETER D. MANAHAN
JOHN B. MURRAY
MARK L. FLEDER
KEVIN J. COAKLEY
THOMAS S. COSMA
KATHLEEN S. MURPHY
PATRICK J. MCAULEY
PETER J. PIZZI*+
KEVIN R. GARDNER
ROBERT E. RYAN
MICHAEL X. MCBRIDE*
JEFFREY W. MORYAN
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PETER J. SMITH*
WILLIAM P. KRAUSS
BRIAN G. STELLER
PHILIP F. MCGOVERN, JR.
KAREN PAINTER RANDALL
LIZA M. WALSH
JOHN P. LACEY*
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ANGELA A. IUSO*
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BRENDAN JUDGE
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CHARLES J. HARRINGTON III+
STEPHEN V. FALANGA*
TRICIA O'REILLY*
ANTHONY F. VITIELLO*+
MARC D. HAEFNER
JONATHAN P. MCHENRY
BRAD D. SHALIT*
M. TREVOR LYONS*
CRAIG S. DEMARESKI*
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MITCHELL W. TARASCHI
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OWEN C. MCCARTHY*
PATRICIA A. LEE*+
AGNIESZKA ANTONIAN*
MICHAEL MICELI
CHRISTOPHER J. TUCCI+
NEIL V. MODY*
STEVE BARNETT*
THOMAS M. SCUDERI*
JOSEPH M. MURPHY*
NANCY A. SKIDMORE*
CHRISTINE S. ORLANDO
JENNIFER C. CRITCHLEY*
PATRICK S. BRANNIGAN*
CHRISTINE I. GANNON*
ANDREW C. SAYLES*
WILLIAM D. DEVEAU*

*ALSO ADMITTED IN NEW YORK
+ALSO ADMITTED IN PENNSYLVANIA
-ONLY ADMITTED IN NEW YORK
PLEASE REPLY TO ROSELAND, NJ

COUNSEL

JOHN W. BISSELL
EUGENE J. CODEY, JR.
FRANCIS J. ORLANDO
FRANCIS E. SCHILLER*
EUGENE P. SQUEO*
BRIAN P. MORRISSEY-
NOEL D. HUMPHREYS*
ANTHONY ROMANO II*

DOUGLAS J. SHORT*
JAMES M. MERENDINO
MICHELE T. TANTALLA*
HECTOR D. RUIZ*
PHILIP W. ALLOGRAMENTO III*
STEPHEN D. KESSLER
CHRISTOPHER ABATEMARCO*
ANTHONY J. CORINO*
INGRID E. DA COSTA
MEGHAN BARRETT BURKE*
RUKHSANAH L. SINGH*
BRITTANY E. MIANO*
STACIE L. POWERS*
NICOLE B. DORY*
MICHAEL BOJBASA-
CHRISTOPHER M. HEMRICK*
SUSAN KWIATKOWSKI*
MELISSA D. LOPEZ
ANDREW L. BARON*
JASON D. FALK*
MICHAEL J. SHORTT+
VICTORIA N. MANOUSHAGIAN*

KARIN I. SPALDING*
JODI ANNE HUDSON*
RICHARD A. JAGEN
JASON E. MARX*
ALEXIS E. LAZZARA
GAIL GOLDFARB*
THOMAS VECCHIO+
DANIEL B. KESSLER*
ROBERT A. VERDIBELLO*

MEGHAN K. MUSSO*
BRENDAN W. CARROLL*
ELEONORE OFOSU-ANTWI*
EDMUND J. CAULFIELD*
SYDNEY J. DARLING*
NEIL V. SHAH*
STEPHEN R. TURANO*
STEVEN A. KROLL*
ROBERT M. DIPISA*
MATTHEW A. BAKER+
MICHAEL J. CREEGAN*
THOMAS M. BLEWITT, JR.+
BRIAN S. WOLFSON
MARY F. HURLEY
DANIELLE M. NOVAK+
KATELYN O'REILLY
JAMES E. FIGLIOZZI-
MATTHEW D. FIELDING*
MELISSA L. HIRSCH+
MARIEL L. BELANGER*
NICHOLAS W. URCIUOLI
KERRY C. DONOVAN
GENEVIEVE L. HORVATH

May 17, 2013

VIA ECF AND FIRST CLASS MAIL
Honorable Esther Salas, U.S.D.J.
United States District Court for the District of New Jersey
Martin Luther King, Jr. Fed. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07101

Re: Roche Palo Alto LLC et al. v. Lupin Pharm., Inc. et al.
Civil Action No. 2:10-3561 (ES/SCM)

Dear Judge Salas,

Pursuant to the Court's Order, Plaintiffs hereby respond to Lupin's objections to Dr. Davis's May 9, 2013 trial testimony. In its May 14, 2013 letter to the Court, Lupin maintains two categories of objections. As discussed below, neither objection is proper.

Lupin objects as outside the scope to the following question from Plaintiffs' counsel: "Is there any PK data, pharmacokinetic data, that shows successful control release, even of these two zwitterions in vivo in Oren?" (Lupin's Ltr. at p. 3; *see* 5/9/2013 Trial Tr. at 44:22-24.)

The testimony elicited by counsel's question is squarely within the scope of Dr. Davis's August 15, 2012 expert report, in which Dr. Davis expressly opined that the Oren patent disclosed no pharmacokinetic (PK) data and no *in vivo* data: "While this reference does disclose formulations containing these two ingredients and includes some dissolution data, ***the patent does not include any pharmacokinetic data to demonstrate that the formulations are capable of providing therapeutically effective levels of the zwitterionic drugs in vivo***." (8/15/2012 Davis Resp. Rpt. at ¶ 110 (emphasis added).) Thus, Lupin's objection has no basis and should be overruled.

Lupin also objects to the following questions from Plaintiffs' counsel as outside the scope of Dr. Davis's expert reports:

- "In your expert opinion, Dr. Davis, would the Oren patent, in combination with any of the other prior art asserted by Lupin, render the formulation limitations of the asserted claims obvious?" (5/9/2013 Trial Tr. at 45:10-13.)
- "In your expert opinion, would the Howard patent in combination with any other prior art asserted by Lupin render the formulation [limitations] of the asserted claims obvious?" (*Id.* at 48:9-12.)
- "In your expert opinion, Dr. Davis, [would] the Dow patent in combination with any of the other prior art asserted by Lupin render the limitation, the formulation limitation[s], [of] the asserted claims obvious[?]" (*Id.* at 52:6-10.)
- "Go back to M[a]cFarlane, in your expert opinion, would McFarlane, in combination with any [of] the prior art asserted by Lupin, render the formulation element[s] of the asserted claims obvious?" (*Id.* at 59:21-24.)

(*See* Lupin'sLtr. at p. 1.) Because Dr. Davis's testimony in response to these questions does not exceed the scope of his August 15, 2012 expert report, Lupin's objection should be overruled.

Contrary to Lupin's characterization, counsel for Plaintiffs did not ask Dr. Davis whether "the asserted claims were not obvious in view of '***any of*** the prior art asserted by Lupin.'" (*See* Lupin'sLtr. at p. 1 (emphasis added by Lupin).) Instead, as the trial transcript shows, the questions were directed only to the specific ***formulation art*** discussed by Dr. Davis, in combination with any of the other prior art asserted by Lupin, and only to the ***formulation limitations*** of the asserted claims. Thus, the issue is whether Dr. Davis's testimony regarding whether the ***formulation art*** relied on by Dr. Chambliss, in combination with any of the other prior art asserted by Lupin, would render the ***formulation limitations*** of the asserted claims obvious is within the scope of Dr. Davis's expert report. It is.

The prior art asserted by Lupin falls into two categories—formulation art and non-formulation art. At the trial, Lupin's formulation expert, Dr. Chambliss, only relied on 5 pieces of formulation art during his direct testimony: Chang & Robinson (DTX-540), the MacFarlane patent (DTX-5), the Oren patent (DTX-379), the Howard patent (DTX-72), and the Dow patents (DTX-29 (Dow '299 patent) and DTX-535 (Dow '988 patent)). There is no dispute that Dr. Davis discussed each of these references in his August 15, 2012 report. (*See, e.g.*, 8/15/2012 Davis Resp. Rpt at ¶¶ 62, 63, 99, 100, 124, 125 (Chang & Robinson), 108-111 (Oren), 117-119 (Howard), 126-128 (MacFarlane), and 103-107 (Dow).) Nor can Lupin dispute that Dr. Davis's opinion regarding non-obviousness of the formulation limitations of the asserted claims in view of any combination of the ***formulation art*** presented by Dr. Chambliss at the trial is squarely within his August 15, 2012 expert report. (*See* 8/15/2012 Davis Resp. Rpt. at ¶¶ 154-264 (addressing non-obviousness of the asserted claims).)

To the extent Lupin's complaint is about Dr. Davis's testimony regarding the effect of combining additional, ***non-formulation art*** not discussed in his report, it is a non-issue because the testimony elicited was limited to the ***formulation limitations*** of the asserted claims.

For Lupin to make out an obviousness case with respect to the formulation limitations of the asserted claims, Lupin necessarily will need to rely on one or more of the formulation art presented by Dr. Chambliss at the trial. Since none of the formulation art—whether alone or in combination with one another—renders the formulation limitations obvious, adding more non-formulation art of course will not make these limitations obvious. Such a conclusion is just common sense and is within the scope of the opinions disclosed in Dr. Davis's August 15, 2012 report.

Because Lupin's objections to Dr. Davis's May 9, 2013 testimony have no merit, Plaintiffs respectfully request that the Court overrule Lupin's objections.

We thank the Court for its continued attention to this matter.

Respectfully submitted,

s/ Liza M. Walsh

Liza M. Walsh

cc: All Counsel of Record (via ECF and Email)